REMARKS/ARGUMENTS

Claims 1 and 19-42 were examined. Claims 1 and 36 are amended. No claims are canceled. No claims are added. Examination and reconsideration of all pending claims are respectfully requested.

Rejection of Claims Under 35 U.S.C. § 112, second paragraph

Claim 36 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Per the Examiner's suggestion, Applicant has amended claim 36 to depend from independent claim 32. Claim 36 should now be clear and in condition for allowance.

Double Patenting Rejection

Claims 1 and 19-27 are rejected under the judicially created doctrine of obviousness-type doubling patenting as being unpatentable over claims 1-10 and 17-22 of commonly owned U.S. Patent No. 6,331,191.

To overcome such a rejection, Applicant submits herewith a Terminal Disclaimer disclaiming the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156, of prior Patent No. 6,331,191. Consequently, Applicant respectfully requests that the Examiner remove the obviousness-type double patenting rejection and allow claims 1 and 19-27.

Rejection of Claims Under 35 U.S.C. § 102

Claims 1, 19-22, 24-26, 28 and 30 are rejected as allegedly being anticipated by U.S. Patent No. 5,931,865 to Silverman et al. Such rejections are traversed in part and overcome in part as follows.

Amended claim 1 recites an endovascular graft for supporting a preselected length of a patient's weakened body lumen comprising a plurality of separate graft members that are configured to be separately layered in a deployment state in the weakened body lumen with at least two of the graft members having a length greater than the preselected length of the patient's weakened body lumen. Silverman et al. does not describe or suggest such an endovascular graft.

As described in the specification of the present application, the endovascular graft of the present invention advantageously allows each individual thin wall graft member to be constructed with less bulk and material mass than would be required for a single component graft of similar length. This allows each separate thin wall graft member to have a smaller more flexible profile in a compressed or constricted state and be deliverable through a smaller and more flexible delivery system which improves access to preselected lengths of compromised or diseased body lumens. *See* page 4, line 11 to page 5, line 2 of the present application.

In contrast, Silverman et al. describes a leak resistant tube that comprises an interference fit between an inner tube element 12 and an outer tube element 14 such that relative movement between the tube elements is allowed. During manufacturing, as described throughout the specification of Silverman et al., the inner and outer tube elements are each placed over a mandrel and positioned relative to each other. (S*ee for example* col. 8, lines 3-31 and col. 9, line 60 to col. 32). Silverman et al. further describes in the specification at col. 5, lines 4-16 and col. 5, lines 47-60 that the tube elements have longitudinal stress differentials established between the two tube elements so as to provide the leak-resistant capability. For example, Silverman et al. describes applying a longitudinal tensile strain to the first tube element and applying a longitudinal compressive stress to the second tube element to create the interference fit. There is no description or suggestion of separately layering the graft members in the body. In fact, for such a configuration described in Silverman et al., it would appear that Silverman et al. requires that the first tube element and second tube element be coupled to each other prior to deployment in the body lumen so that the stress differential can be established between the two tube elements.

It is well established that "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385(CCPA 1970). Independent claim 1 explicitly requires that the plurality of separate graft members be configured to be separately layered in a deployment state in the weakened body lumen. Silverman et al. only appears to describe a graft that has first and second tube elements 12, 14 that are delivered into the body lumen simultaneously. If the Examiner is to maintain the rejection of independent claim 1, Applicant respectfully requests that the Examiner specifically point out where Silverman et al. describes "a plurality of graft members that are configured to be

separately layered in a deployment state in the weakened body lumen." Absent such a showing, independent claim 1 is allowable over Silverman et al.

Independent claim 19 recites a graft for treating a length of a patient's body. The graft comprises a plurality of thin wall graft members configured to be separately layered in a deployed state in the body lumen. At least two layers of the thin wall graft members are present across the length of the patient's body lumen being treated. As noted above, Silverman et al. only appears to describe a multi-layered graft in which the two layers are delivered into the body simultaneously. Silverman et al. does not appear to describe or suggest a plurality of thin wall graft members that are "configured to be separately layered in a deployed state in the body lumen." Consequently, independent claim 19 is allowable. For at least the same reasons dependent claims 20-22, 24-26, 28, and 30 should also be allowable over Silverman et al.

Claims 1, 19, 21, 28-32, 35-39 and 42 are rejected as being allegedly anticipated by U.S. Patent No. 5,639,278 to Dereume et al. Such rejections are traversed as follows.

As noted above, amended independent claim 1 recites an endovascular graft for supporting a preselected length of a patient's weakened body lumen comprising a plurality of separate graft members that are configured to be separately layered in a deployment state in the weakened body lumen with at least two of the graft members having a length greater than the preselected length of the patient's weakened body lumen. Dereume et al. fails to describe or suggest the endovascular graft recited in independent claim 1.

Specifically, Dereume et al. does not describe or suggest the claim limitation "at least two of the graft members having a length greater than the preselected length of the patient's weakened body lumen." Instead, as shown in Figures 18-25 of Dereume et al., a trunk component 101, tubular graft component 108 and tubular graft component 115 all appear to have lengths that are less than the preselected length of the patient's weakened body lumen. Hence, Dereume et al. does not describe or suggest all of the elements of claim 1, and independent claim 1 should be allowable over Dereume et al.

Independent claim 19 recites a graft for treating a length of a patient's body. The graft comprises a plurality of thin wall graft members configured to be separately layered in a deployed state in the body lumen. At least two layers of the thin wall graft members are present

across the length of the patient's body lumen being treated. Dereume et al. does not describe or suggest such a graft.

Specifically, Dereume et al. does not describe or suggest a graft that comprises "at least two layers of thin wall graft members present across the length of the patient's body lumen being treated". As shown by Figures 18-25, Dereume et al. provides a combination of three graft components 101, 108, 115, in which the leg components 108, 115 extend into the legs 109, 113 of the trunk component 101. The overlapped portion between trunk component 101 and leg components 108, 115 (Figs. 21-24) is not present across the length of the patient's body lumen being treated, as is required by claim 19. Consequently, independent claim 19 should also be allowable over Dereume et al. For at least the same reasons, dependent claims 21 and 28-31 are allowable over Dereume et al.

Claim 32 recites a method of deploying an endovascular graft within a body lumen. The method comprises deploying a first graft member at a section of the patient's body lumen being treated. At least one additional graft member is delivered within a longitudinal lumen of the deployed first graft member. The at least one additional graft member is deployed within the longitudinal lumen of the deployed first graft member such that an overlapped portion of the first graft member and the at least one additional graft member span the section of the patient's body lumen being treated.

In contrast, as shown by Figures 18-25, Dereume et al. illustrates the combination of the three graft components 101, 108, 115, in which the overlapped portion between grafts 101, 115, 108, spans less than the section of the patent's body being treated. As such, Dereume et al. does not provide all of the elements of claim 32. Consequently, independent claim 32 is allowable over the cited art. For at least the same reasons, dependent claims 33-37 are also allowable.

Independent claim 38 provides a multi-layered endovascular graft that comprises a first graft member comprising a membrane and a support structure that define a lumen and one or more additional graft members that each comprise a membrane and a support structure. One or more additional graft members are configured to be layered *in situ* within the lumen of the first graft member such that an overlapped portion of the first graft member and the one or more additional graft members spans a length of a compromised portion of a body lumen.

Dereume et al. does not describe or suggest an endovascular graft that comprises an overlapped portion of the first graft member and the one or more additional graft members that spans a length of a compromised portion of a body lumen. As noted above, the graft components 101, 108, 115 are not overlapped over the length of the compromised portion of the body lumen, but instead only overlap over legs 109, 113 of trunk component 101. Such an overlap portion does not span a length of the compromised portion of the body lumen. Consequently, independent claim 38 is allowable. For at least the same reasons, dependent claims 29-42 are allowable.

Rejection of Claims Under 35 U.S.C. §103(a)

Dependent claims 23, 27, 33-34 and 41 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dereume et al. Such rejections are traversed as follows.

In addition to relying on allowable base claims, dependent claims 23, 27, 33-34 and 41 recite novel aspects not described or suggested by Dereume et al.

Claims 23 and 27 recite that the thin wall graft members comprise a longitudinal axis and are configured to expand to a transverse dimension relative to the longitudinal axis of up to about 40 mm and can be constrained to a minimum transverse dimension of down to about 3 mm. Claim 41 recites that at least one of the membranes of the first graft member and the membrane(s) of the one or more additional graft members has a thickness of between approximately 0.002 inches and 0.008 inches. Such dimensions are not suggested or described by the cited art. As is described in the specification at page 4, line 11 to page 5, line 2, the plurality of separately deployable graft members allows for each separate thin wall graft member to have a smaller, more flexible profile in a compressed or constricted state and be deliverable through a smaller and more flexible delivery system, while still providing sufficient mechanical strength to support the preselected length of a patient's body lumen. Because such dimensions of the graft members provide benefits not described or suggested by the Dereume et al., such claims should be allowable.

Dependent claim 33 recites that the at least one additional graft member comprises an inner most graft member that extends longitudinally beyond a proximal end and a distal end of the first graft member and directly engages the body lumen proximally and distally

of the section of the patient's body lumen being treated. As is described in the specification at page 5, line 16 to page 6, line 2, such an embodiment advantageously provides a smooth transition into the graft for blood flow and a smoother inner surface for the graft in its final deployed state. Dereume et al. does not describe or suggest such limitations. Consequently, claim 33 should be allowable.

Claims 34 recites that the innermost graft is anchored both proximally and distally beyond the section of the patient's body lumen being treated. Dereume et al. does not describe or suggest such an embodiment. Instead, as shown in Figs. 21 to 25, none of graft components 101, 108, 115 are anchored both proximally and distally beyond the section of the patient's body lumen being treated. Instead, graft component 101 is only anchored at the distal end of the weakened vessel, and tubular components 108, 115 appear to be anchored in the trunk component 101. Consequently, claim 34 should be allowable over Dereume et al.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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